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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,813	07/22/2003	Winthrop D. Childers	10008113-4	7780

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EXAMINER	
KOCH, GEORGE R	

ART UNIT	PAPER NUMBER
1734	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,813	CHIILDERS	
	Examiner	Art Unit	
	George R. Koch III	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 12-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/15/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 12 and 19-21, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/375,794 in view of Burns (US 5,284,133). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other.

Claim 1 includes an ejector, a variant of the fluid drop generator, and a controller, a variant of the control. Claim 1 does not recite a reservoir. However, Burns recites a reservoir (see Figure 4a), which provides a replaceable medicine source. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to

have utilized such a reservoir in order to achieve ease in replacement of the medicine source.

Claim 19-21 are an obvious variation of claims 1 and 2 of application 10/375,794.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 12 and 19-21, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10/777,448.

The limitations of claim 12 and 19-21 are obvious but not identical to the limitations of claim 1 of US 10/777,448. The reservoir corresponds to the supply, the drop generator with the ejector, and the two controllers are obvious variations of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 12, 17 and 19-21, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10/777,449.

The limitations of claim 12 are obvious but not identical to the limitations of claim 1 of US 10/777,448. The reservoir corresponds to the supply, the drop generator with the ejector, and the two controllers are obvious variations of each other.

As to claim 17, claim 7 of US 10/777,449 recites control by weight.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 12, and 19-21, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 11/017,163.

The limitations of claim 12 are obvious but not identical to the limitations of claim 1 of US 10/777,448. The reservoir corresponds to the reservoir, the drop generator with the ejector, and the controllers is an obvious variation of the electronic circuitry.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12, 13, 16, 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wirch (US 5,881,716).

As to claim 12, Wirch discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 8) fluidically coupled to the reservoir (item 5); and a control (columns 2-3) activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium. The exact dose amount can be selected by an operator (abstract; Figure 5, column 1, lines 10, 21, 34, 44).

As to claim 13, Wirch discloses that the liquid reservoir is replaceable (column 2, line 28).

As to claim 16, Wirch discloses that the system can operate by remote control (see column 2, line 22).

As to claim 19, Wirch discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 2, line 59 to column 3, line 48).

As to claim 20, Wirch discloses a replaceable cartridge (see column 2, lines 26-28) capable of functioning as claimed, the cartridge comprising a reservoir (item 5) and a fluid drop generator (item 8) capable of being used as claimed.

As to claim 21, Wirch discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 2, line 59 to column 3, line 48).

As to claim 22, the control unit of Wirch is capable of storing the identity of the pharmaceutical component.

As to claim 23, Wirch discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1).

As to claim 24, Wirch discloses that the information storage elements specify the number of drops to be dispensed (see column 3, lines 35-40, which recite "droplets per time unit")).

As to claim 25, Wirch discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1).

8. Claims 12-15, 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Voges (US 5,894,841).

As to claim 12, Voges discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 14) fluidically coupled to the reservoir (item 10); and a control (item 16) activating the fluid drop generator to eject a variably selected quantity of the

pharmaceutical component onto the medium. The exact dose amount can be selected by an operator.

As to claim 13, the liquid reservoir is inherently replaceable, and also discloses that the components can be changed (see column 10, lines 43-63, which recites that the parts are replaceable).

As to claim 14, Voges discloses that the dispenser can be provided with a plurality of cartridges or reservoirs (column 11, line 67), each which can hold a different component.

As to claim 18, Voges discloses that the dispenser can be provided with a plurality of chambers (column 12, lines 1-2) each which can hold a different component.

As to claim 19, Voges discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 11, lines 1-60).

As to claim 20, Voges discloses a replaceable cartridge (see column 10, lines 43-63, which recites that the parts are replaceable) capable of functioning as claimed, the cartridge comprising a reservoir (item 10) and a fluid drop generator (item 14) capable of being used as claimed.

As to claim 21, Voges discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 11, lines 1-60).

As to claim 22, the control unit of Voges is capable of storing the identity of the pharmaceutical component.

As to claim 23, Voges discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1 and 2).

As to claim 24, Voges discloses that the information storage elements specify the number of drops to be dispensed (see column 12, line 7, which discloses "successive medications in a dose").

As to claim 25, Voges discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1 and 2).

As to claim 26, Voges discloses that the dispenser can be provided with a plurality of chambers (column 12, lines 1-2) each which can hold a different component.

9. Claims 12-13, 17, and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Moldavsky (US 6,061,608).

As to claim 12, Moldavsky discloses an apparatus for capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (i.e., pump 25 in which the liquid 17 is stored) capable

of containing one fluid pharmaceutical component, a fluid drop generator (item 23) fluidically coupled to the reservoir; and a control (item 22 and 30) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

As to claim 13, the apparatus of Moldavsky is inherently replaceable.

As to claim 17, Moldavsky discloses a weight detector (item 21, and see column 3 and 4) for detecting and outputting signals corresponding to the weight of the substrate (which can be the claimed substrate) after the liquid (which can be the component) is dispensed onto the substrate.

As to claim 19, Moldvasky discloses a control (items 22 and 30) which functions as the claimed information storage element.

As to claim 20, Moldavsky as applied above discloses the reservoir and fluid drop generator. Furthermore, the apparatus of Moldavsky is inherently replaceable.

As to claims 21-22, the control of Moldavsky (items 22 and 30) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 23, the drop generator of Moldavsky is integrally coupled to the reservoir (i.e., pump - see Figure 1).

As to claims 24, the control of Moldavsky (items 22 and 30) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 25, the drop generator of Moldavsky is integrally coupled to the reservoir (i.e., pump - see Figure 1).

10. Claims 12-13, and 19-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns (US 5,284,133)

As to claim 12, Burns discloses an apparatus for capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (item 10) capable of containing one fluid pharmaceutical component, a fluid drop generator (nebulizer - recited in column 10, lines 35-51) fluidically coupled to the reservoir; and a control (Figure 2, and see column 9) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

As to claim 13, the apparatus of Burns is replaceable (see column 9, lines 1-8, which disclose placing multiple canisters).

As to claim 19, Burns discloses a control (items 22 and 30) and chip (item 25) which functions as the claimed information storage element.

As to claim 20, Burns as applied above discloses the reservoir and fluid drop generator. Furthermore, the apparatus of Burns is replaceable.

As to claims 21-22, the control of Burns (Figure 2) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 23, the drop generator of Burns is integrally coupled to the reservoir (Figure 4a).

As to claims 24, the control of Burns (Figure 2) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 25, the drop generator of Burns is integrally coupled to the reservoir (Figure 4a).

As to claim 26, Burns discloses that the chip stores a parameter identifying the pharmaceutical component (see column 4, lines 60-63).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5,894,841) as applied to claim 14 above.

As to claim 14, Voges discloses that the dispenser can be provided with a plurality of cartridges or reservoirs (column 11, line 67), each which can hold a different

component. Furthermore, as to claim 15, Voges discloses that the fluid generator can have more than one fluid drop generators (see column 10, line 51).

Voges fails to teach that the different fluid drop generators are used for the different medications. However, official notice is taken that it would have been well known and conventional to have linked the multiple drop generators with individual cartridges or reservoirs. One in the art would immediately recognize that connecting the reservoirs to the generators would enable the storage of multiple pharmaceuticals in one device, and multiple dosing regimes, without cross-contamination. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized various generators separately connected to the reservoirs in order to reduce cross-contamination.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Wirch (5,881,716) or Voges (US 5,894,841) as applied to claim 12 above, and further in view of Moldavsky (US Patent 6,061,608).

Neither Wirch nor Voges discloses a weight detector for detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving medium.

Moldavsky discloses a weight detector(item 21) for detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving

medium. Moldavsky discloses that such weight control allows for improvements in the volumetric accuracy and repeatability of the dispensing process (see column 1, lines59-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized such weight controls in the inventions of Wirch or Voges in order to achieve volumetric accuracy and repeatability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Koch III whose telephone number is (571) 272-1230 (TDD only). If the applicant cannot make a direct TDD-to-TDD call, the applicant can communicate by calling the Federal Relay Service at 1-866-377-8642 and giving the operator the above TDD number. The examiner can normally be reached on M-Th 10-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R. Koch III
Patent Examiner
Art Unit 1734

GRK
2/5/2005